

NAME OF THE COURSE		Elective course Understanding clinical trials				
Code		Year of study	1.-4.			
Course teacher	Prof. Ana Marušić	Credits (ECTS)	2			
Associate teachers	Ružica Tokalić, MD, Marin Viđak, MD	Type of instruction (number of hours)	L	S	E	F
			0	15	10	
Status of the course	Elective	Percentage of application of e-learning				
COURSE DESCRIPTION						
Course objectives	To enable students with skills and knowledge necessary for understanding clinical trials					
Course enrolment requirements and entry competences required for the course	There are no requirements – the course is opened to all students.					
Learning outcomes expected at the level of the course (4 to 10 learning outcomes)	<ul style="list-style-type: none"> ▪ To describe the importance of clinical trials ▪ To list and provide examples of different clinical trial designs ▪ To recognize the importance of randomization and blinding ▪ To interpret intention-to-treat and per-protocol analysis ▪ To identify most important outcomes of clinical trials ▪ To describe the basic principles of good clinical practice 					
Course content broken down in detail by weekly class schedule (syllabus)	<p>Each day will start with 3 hours of seminars, followed by 2 hours of practical.</p> <p>Day 1 Seminar: Types of Trial Designs Practical: Registering clinical trials</p> <p>Day 2 Seminar: Randomization and Masking Practical: Good Clinical practice</p> <p>Day 3 Seminar: Outcomes and Analysis Practical: Journal club</p> <p>Day 4 Seminar: Reporting results Practical: CONSORT statement</p> <p>Day 5 Seminar: Beyond clinical trials Practical: Choosing evidence for clinical practice</p>					
Format of instruction	<input type="checkbox"/> lectures <input checked="" type="checkbox"/> seminars <input type="checkbox"/> mixed e-learning <input checked="" type="checkbox"/> independent assignments					
Student responsibilities	Presence at teaching activities: 80% seminars, 100% practicals.					
Screening student work (name the proportion of ECTS credits for each activity so that the total number of ECTS credits is equal to the ECTS value of the course)	Class attendance	0.25	Individual assignments (Course essay)	1.75		

Grading and evaluating student work in class and at the final exam	Seminar and course assignments				
Required literature (available in the library and via other media)	Title	Number of copies in the library	Availability via other media		
	Marušić M, editor. Principles of Research in Medicine. 2 nd ed. Zagreb: Medicinska naklada; 2015.				
	Guyatt G, Rennie D, Meade MO, Cook DJ. Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice. 3. ed. McGraw-Hill Education; 2014.				
	Livingston EH, Lewis RJ. JAMA Guide to Statistics and Methods. 1. ed. McGraw-Hill Education; 2020.				
Optional literature (at the time of submission of study programme proposal)					
Quality assurance methods that ensure the acquisition of exit competences	Quality assessment during classes by students and teachers. Analysis of course examination success. Report of the Committee for quality assurance. External evaluation (reaccreditation assessment from the Agency for Higher Education and Research)				
Other (as the proposer wishes to add)					